

come together to form an assembled cartridge, for a different cartridge design) with dried reagents. FIG. 26 (240) indicates the shape of the double sided adhesive material which is cut away to form channels and sink structures when bonded between two layers of laminate material. The cartridge is then stored in a sealed foil pouch containing desiccant until use.

[0217] PSA protein is diluted to the required concentration in 60 mg/ml BSA in PBS, pH 7.2. A cartridge containing dried reagents is inserted into the 'MST pro meter V1' reader and 8  $\mu$ l PSA is then added to the cartridge to fill the test sample channels. The sample is applied to the cartridge via sample inlet port (226) and fills the channels by capillary force up to the hydrophobic fluidic stop features (229, 228, 239, 237). 5 min binding incubation occurs before the reader brings a permanent magnet to the cartridge where it acts to collect the paramagnetic particles and anything bound to them into the detection area (222, 241). The sealing head of the reader makes a fluid tight seal with input ports of channels 1,2,3,4,5,6 (224, 231, 232, 233, 234, 235 respectively). Whilst the paramagnetic complexes are maintained in place by the magnet, the reader carries out a wash step by expelling air from the syringe pump cartridge (as shown in FIG. 15, bottom image of 6 chamber syringe cartridge) to displace the sample fluid from the channel, and hence remove the unbound latex from the detection area and displace it into the sink (236). The optical reader head then carries out a measurement of the remaining fluorescent signal (from the specific sandwich binding complexes of paramagnetic particles-PSA-fluorescent particles) which remain in air by scanning across the detection areas of each channel (222, 241) (see FIG. 22 for a description of these results).

[0218] Results for Assay 3:

[0219] FIG. 22 shows results for a Total PSA Dry assay performed in the MST Pro Meter and Strip, the meter uses air wash step to expel unbound label from the channel. All the reagents were deposited in the strip. The dynamic range of the Total PSA assay was increased significantly by using a different fluorescent latex label preparation and by reducing the input voltage to the optical detector. The summary results are shown in FIG. 22 where the assay is a full dry assay with all reagents deposited within the strip. The assay range has been extended significantly, the linear response has been increased by 10 times (10 to 100 ng/ml), and this is of great value as some assays require assays with a low limit of detection but a large dynamic range. With such assays linearity is not maintained across the large dynamic range, resulting in reduced assay performance at higher concentrations. The MST Pro platform can overcome this limitation in several ways. For example, non linearity due to optical detector saturation can be overcome by reducing the sensitivity of the optical detector by reducing the input voltage. Therefore if binding is linear, the reduced sensitivity of the optical detector will allow the dynamic range of the assay to be increased further (the meter would contain a PSA calibration curve for the high and low optical detector setting). In comparison, if the non linearity is due to a reagent limitation, two channels of the MST Pro strip could be used to maximize assay performance across the assay range. Reagents developed to make very sensitive measurements that have a limited dynamic range could be deposited in one channel whilst reagents that are less sensitive but allow the dynamic range of the assay to be increased significantly could be deposited in another channel.

Each set of reagents/channel would have its own calibration curve therefore allowing improving assay performance over whole range of the assay.

Assay 4: 2 Step Half Dry Assay (Dried Latex Particles) with Wash and Measurement Carried Out in 'MST Pro Meter V1' Reader

[0220] Reagents are deposited and dried within a 'MST pro strip V1' cartridge as follows:

[0221] 10  $\mu$ l 0.25% functionalized latex 1 (with biotinylated 5A6 bound)

[0222] 10  $\mu$ l 25 mg/ml trehalose in PBS, pH 7.2

[0223] 20  $\mu$ l 300 mg/ml BSA in PBS, pH 7.2

[0224] 10  $\mu$ l 0.1% tween-20 in PBS, pH 7.2

[0225] The above reagents are combined and 1  $\mu$ l of this deposition mix added per channel of a 'MST pro strip V1' cartridge (as shown in FIG. 26). Reagents are deposited at position (223, 242) in each channel and not allowed to enter the detection area (222, 241) (this is achieved by use of a hydrophobic pen line to define the reagent deposition area on a single surface of the laminate cartridge, which is sufficient to prevent reagent spread but not strong enough to prevent sample filling of the fully assembled cartridge). For deposition, the cartridge is half assembled, with only the bottom and middle layer of cartridge bonded together. The reagents are pipetted into the reagent deposition zone of the half assembled test sample channel (see FIG. 26, with reagent deposition zone indicated on the cartridge as point 223, 242). These are dried in an oven at 33 deg C. for 10 min. The top layer of the cartridge is then bonded to the half assembled cartridge to produce a fully assembled three layer cartridge (see FIG. 2 for an example of how the three layers come together to form an assembled cartridge, for a different cartridge design) with dried reagents. FIG. 26 (240) indicates the shape of the double sided adhesive material which is cut away to form channels and sink structures when bonded between two layers of laminate material. The cartridge is then stored in a sealed foil pouch containing desiccant until use.

[0226] In this 2 step assay, the first binding step (functionalized paramagnetic particles with PSA) is carried out in a wet format, before the second binding step (functionalized paramagnetic particles-PSA with functionalized latex 1) occurs using dried functionalized latex 1 within the 'MST pro strip V1' cartridge as follows:

[0227] Step1

[0228] The following reagents are combined:

[0229] 2  $\mu$ l 0.5% functionalized paramagnetic particles (with bound biotinylated 1H12)

[0230] 6  $\mu$ l 30 mg/ml BSA in PBS, pH 7.

[0231] 2  $\mu$ l PSA (diluted in 60 mg/ml BSA in PBS, pH 7.2)

[0232] This first step binding reaction is incubated for 5 min at room temperature before 8  $\mu$ l is added to the cartridge containing dried functionalized latex to fill the test sample channels as shown in FIG. 26. The sample is applied to sample inlet port (226) where it fills the channels up to the fluidic stop features (228, 239, 229) (which are made of hydrophobic ink). 5 min binding incubation occurs before the reader brings a permanent magnet to the cartridge where it acts to collect the paramagnetic particles and anything bound to them into the detection area. The sealing head of the reader then makes a fluid tight seal with input ports of channels 1,2,3,4,5,6 (224, 231, 232, 233, 234, 235 respectively). Whilst the paramagnetic complexes are maintained in place by the magnet, the reader carries out a wash step by expelling